Complete Summary

GUIDELINE TITLE

Recommendations for the establishment of primary stroke centers.

BIBLIOGRAPHIC SOURCE(S)

Alberts MJ, Hademenos G, Latchaw RE, Jagoda A, Marler JR, Mayberg MR, Starke RD, Todd HW, Viste KM, Girgus M, Shephard T, Emr M, Shwayder P, Walker MD. Recommendations for the establishment of primary stroke centers. JAMA 2000 Jun 21;283(23):3102-9. [69 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Acute stroke

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Critical Care
Emergency Medicine
Internal Medicine
Neurological Surgery
Neurology
Pathology
Radiology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Emergency Medical Technicians/Paramedics
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To develop recommendations for the establishment and operation of primary stroke centers as an approach to improve the medical care of patients with stroke.

TARGET POPULATION

Patients with acute stroke [who are initially evaluated and treated in hospital settings]

INTERVENTIONS AND PRACTICES CONSIDERED

1. Primary stroke centers

   Major elements of primary stroke centers:

   - Patient care areas:
     - Acute stroke teams
     - Written care protocols
     - Emergency medical services
     - Emergency department
     - Stroke unit
     - Neurosurgical services
   - Support services:
     - Commitment and support of medical organization; a stroke center director
     - Neuroimaging services
     - Laboratory services
     - Outcome and quality improvement activities
     - Continuing medical education
2. Comprehensive stroke centers

MAJOR OUTCOMES CONSIDERED

- Survival rates
- Treatment efficacy
- Reduced complications
- Efficiency of care

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developers conducted a comprehensive review of the English-language literature to identify articles dealing with formation, function, and outcomes of centers for various medical conditions, with a focus on stroke centers and trauma centers. The guideline developers searched MEDLINE from 1966 through March 2000. This review was also used to identify evidence-based interventions shown to be efficacious for treatment of patients with acute stroke and that would require a specialized infrastructure for implementation. Publications of randomized clinical trials, care guidelines, or appropriate observational studies were selected.

NUMBER OF SOURCE DOCUMENTS

More than 600 articles

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

In reviewing the literature, particular attention was paid to issues such as outcomes, the economic impact on the health care system, patient comfort, and logistical aspects of patient care. These publications were reviewed initially by one of the authors (M.J.A.). These data and subsequent recommendations were then reviewed and analyzed by Brain Attack Coalition members to help develop recommendations for key elements of a primary stroke center.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

In the setting of managed care and specified networks of care facilities, it is important that patients receive the proper care for their medical conditions. When patients with acute stroke can be taken to a number of hospitals within a specific network, it is hoped that they would be taken to a designated stroke center, because doing so would optimize their care and may result in cost savings. For example, if the stroke center designation increased the appropriate use of tPA, there could be substantial cost savings for a managed care system. One study estimated that for every 1000 patients with stroke treated with tPA, there is an overall savings of almost $5 million. Such designations also could aid managed care plans in hospital selection in that they could make an effort to include a certain number of hospitals with stroke centers as part of their care network.

It is difficult to determine accurately the costs for a primary stroke center because of the paucity of published data on most aspects of these specific costs. It is likely that the start-up costs would be higher than for annual operations once the infrastructure was in place. The estimated annual operational costs may range from $8000 to more than $200,000 depending on current staffing levels, the need for salary supplements, and the presence of various programs and infrastructure. In general, these expenditures are relatively small compared with the annual budget for most hospitals. It is possible that most costs could be recouped by shortening the length of stay for patients with stroke by just 1 day or by preventing several recurrent strokes in the course of a year. By reducing complications and improving patient status at discharge, the savings to the health care system could be substantial.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Members of the Brain Attack Coalition reviewed, assessed, and modified each recommendation in the context of current practice parameters, with special attention to improving the delivery of care to patients with acute stroke, cost effectiveness, and logistical issues related to the establishment of primary stroke centers. In all cases, a consensus was reached among all Brain Attack Coalition participants before an element was added to the list of recommendations.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Major Elements of a Primary Stroke Center

Patient care areas
Acute stroke teams
Written care protocols
Emergency medical services
Emergency department
Stroke unit*
Neurological services
Support services
Commitment and support of medical organization; a stroke center director
Neuroimaging services
Laboratory services
Outcome and quality improvement activities
Continuing medical education

* A stroke unit is only required for those primary stroke centers that will provide ongoing in-hospital care for patients with stroke.

(1) Acute Stroke Teams
The formation of an acute stroke team is an important step for organizing and delivering care to patients with acute stroke. The team may be staffed by a variety of health care professionals depending on the resources available at a particular facility. Different members may alternate serving on the team depending on staffing levels and patient needs. Although the acute stroke team does not have to be led by or include a neurologist or neurosurgeon, it is recommended that the team include personnel with experience and expertise in diagnosing and treating patients who have cerebrovascular disease. At a minimum, the team should include a physician and another health care professional (i.e., nurse, physician's assistant, nurse practitioner) who are available 24 hours everyday. It is recommended that the team respond to patients with acute stroke in the emergency department, in other hospital wards, or in a clinic within or adjacent to the hospital. There must be a specific and well-organized system for rapidly notifying and activating the team to evaluate patients presenting with symptoms suggestive of an acute stroke. A member of the team should be at the patients' bedside within 15 minutes of being called. The precise organization of the team would vary by institution but should include these key elements.

The existence and operations of the team should be supported by a written document that provides information about administrative support, staffing,

notification plans, response times, and the number of patients seen. A log should be kept that documents call times, response times, patient diagnoses, treatments, and outcomes. This log could be kept by the team leader or a designee and be used for quality improvement monitoring.

(2) Written Care Protocols
For a primary stroke center, written care protocols should include the emergency care of patients with ischemic stroke and hemorrhagic stroke, including stabilization of vital functions, initial diagnostic tests, and use of medications (including but not limited to intravenous tissue plasminogen activator [tPA] treatment). These protocols could be based on previously published guidelines or could be developed by a multidisciplinary team organized by the stroke center.

Documentation should include written care protocols for acute stroke that are available in the emergency department and other areas likely to evaluate and treat patients with stroke. These protocols should be reviewed and updated at least once a year. It is understood that individual physicians and patients may not follow a particular protocol due to variations in the clinical situation and preferences of the patient, physician, or both. Adherence to the stroke protocol could be a component of quality improvement.

(3) Emergency Medical Services
Substantial evidence supports the key role of emergency medical services personnel in providing timely care to patients with stroke. Because emergency medical services have such a vital role in the chain of survival for patients with stroke, it must be an integral component of a primary stroke center. For example, a call for a possible stroke should be assigned a high priority to ensure rapid evaluation and transport.

It is vital that the emergency medical services system be integrated with the stroke center. The stroke center should be able to communicate effectively with emergency medical services personnel in the out-of-hospital setting during transportation of a patient experiencing an acute stroke. The emergency department should be able to efficiently receive and triage patients with stroke arriving via emergency medical services. The stroke center staff should support and participate in educational activities involving emergency medical services personnel. The integration of an emergency medical services system with a stroke center should be documented by a written plan for transporting and receiving patients with stroke via emergency medical services, a letter of cooperation between the stroke center and the emergency medical services system, and evidence of cooperative educational activities at least twice a year.

(4) Emergency Department
Emergency department personnel should be trained in diagnosing and treating all types of acute stroke. The emergency department should have well-established lines of communication with emergency medical services personnel and should be able to prepare for the arrival of patients with strokes from the emergency medical services system. Emergency department personnel should be familiar with the acute stroke team, how it is activated and how it functions. Some emergency department personnel, most likely, will be members of the team. The emergency department staff should have written protocols for triage and

treatment of patients experiencing an acute stroke (i.e., use of thrombolytic therapy, management of increased intracranial pressure and blood pressure).

Emergency department personnel, including physicians and nurses, should participate in educational activities related to stroke diagnosis and treatment at least twice a year. Written documents that detail the emergency department procedures for managing patients with acute stroke should be provided. Such documentation should include policies and statements about how the emergency department is integrated with the entire stroke center, along with treatment algorithms and flow charts.

(5) Stroke Unit
Primary stroke centers that intend to provide care beyond the hyperacute period (i.e., longer than the emergency department evaluation and emergency therapy) should provide such care in a stroke unit setting. Stroke centers that do not intend to provide care beyond the hyperacute period do not require stroke units.

Stroke units do not have to be distinct hospital wards or units, but they should be staffed and directed by personnel (i.e., physicians, nurses, speech therapists, physical therapists) with training and expertise in caring for patients with cerebrovascular disease. A stroke unit usually would include other infrastructure such as continuous telemetry (preferably computerized), written care protocols, and the capabilities to monitor blood pressure continuously and noninvasively. Some stroke units may have the capability of using arterial catheters for monitoring during the administration of vasoactive agents, although these interventions usually are performed in an intensive care unit. Stroke units do not have to include all of the features of an intensive care unit, although some may overlap. For hospitals in which the stroke unit is part of an established intensive care unit, the intensive care unit nurses should receive specific training in caring for patients with stroke. Physicians caring for patients with stroke in an intensive care unit could be intensivists or other physicians; the key issue is that they have training and expertise in caring for such patients. However, the vast majority of patients with stroke do not require the services of a typical intensive care unit. Monitoring patients with stroke can be performed in a stroke unit or an intensive care unit, depending on the staffing levels and cardiovascular monitoring capabilities of the unit.

For primary stroke centers with stroke units, documentation should be provided about the staffing and operations of the unit, including admission and discharge criteria, care protocols, patient census, and outcome data.

(6) Neurosurgical Services
For the purposes of a primary stroke center, neurosurgical care for the patient should be available within 2 hours of when it is deemed clinically necessary. This means that either the patient could be transferred to another facility with a neurosurgeon or the neurosurgeon could be on-call at the initial hospital and able to see the patient within 2 hours.

Hospitals providing neurosurgical care must have an operating room staffed 24 hours everyday with the necessary equipment and support personnel (i.e., anesthesiology, radiology, pharmacy) to perform neurosurgical procedures that patients experiencing a stroke might require urgently. Neurosurgical coverage

should be documented in a written plan approved by the covering neurosurgeon, stroke center leaders, and involved facilities. A call schedule should be readily available in the emergency department and to stroke center personnel. A written transfer plan and protocol should be developed, reviewed, readily available, and agreed on in advance by the transferring and receiving facilities.

(7) Commitment and Support of the Medical Organization
A primary stroke center should have a designated medical director who has training and expertise in cerebrovascular disease. The director does not have to be neurologist but should have sufficient knowledge of cerebrovascular disease to provide leadership and guidance to the program. Examples of such knowledge might include 2 or more of the following criteria: (1) completion of a stroke fellowship, (2) participation (as an attendee or faculty) in at least 2 regional, national, or international stroke courses or conferences each year, (3) 5 or more peer-reviewed publications on stroke, (4) 8 or more continuing medical education credits each year in the area of cerebrovascular disease, and (5) other criteria agreed on by local physicians and hospital administrators.

Physician staffing for a primary stroke center should include clinicians with training and expertise in treating patients with cerebrovascular disease. Evidence of such training could include one or more of the criteria listed above.

Evidence of administrative support can be provided by written documents that include a statement of support from the administration, an organizational chart, a listing of available infrastructure for the stroke center, and a budget. The curricula vitae of key personnel should be provided to demonstrate their training and expertise in cerebrovascular disease.

(8) Neuroimaging
Primary stroke centers must have the capability of performing either a cranial computed tomographic scan or a brain magnetic resonance imaging scan within 25 minutes of the order being written. These imaging capabilities must be available 24 hours everyday.

Also, physicians experienced in interpreting computed tomographic and magnetic resonance imaging studies must be available to read these scans within 20 minutes of their completion. These physicians may include radiologists with experience interpreting cranial computed tomographic or magnetic resonance imaging films, as well as neurologists and others with expertise and experience with these techniques. Such persons can be available in the hospital or by remote access (i.e., teleradiology). Teleradiology could be linked to radiologists (or other physicians) at home or at a remote site such as a comprehensive stroke center. There should be written documentation that such scans were performed and read within the specified times and that such scans can be performed 24 hours everyday. A log book that documents such scans with time parameters and interpretation is one way to document and monitor this capability.

(9) Laboratory Services
Efficient diagnosis and treatment of patients with stroke requires the availability of standard laboratory services 24 hours everyday. These include the ability to perform and report complete blood cell counts, blood chemistries, and coagulation studies rapidly. Also, a primary stroke center should be able to complete an

electrocardiogram and chest radiograph rapidly. It is recommended at primary stroke centers that these laboratory results be completed within 45 minutes of their being ordered. A letter of support from the laboratory director, along with written documentation that the necessary laboratories and services can complete the examinations within the recommended time, should be provided.

(10) Outcomes and Quality Improvement
Stroke centers should have a database or registry for tracking the following: number of patients and type of stroke each patient experienced, type of treatments provided, time lines for providing treatments, and measurement of outcomes. A written system should be in place so that such data can be systematically collected, reviewed, and acted upon. Specific benchmarks for comparisons should be established. For example, published guidelines recommend that the door-to-needle time for the use of intravenous tissue plasminogen activator treatment in patients with stroke should be no more than 60 minutes.

Studies have documented the usefulness of quality improvement programs for the care of patients with stroke. The stroke center should select at least 2 relevant patient-care issues to serve as benchmarks each year. Prespecified committees should meet, review, and modify practice patterns (if needed) at least 3 times a year. Documentation should be provided about specific benchmarks, quality improvement areas, and minutes from at least biannual meetings of the appropriate committee(s).

(11) Educational Programs
Due to the rapidly changing nature of diagnosis and management of cerebrovascular disease, it is recommended that the stroke center's professional staff (including staff working in a stroke unit) receive at least 8 hours a year of continuing medical education credit (or an equivalent amount of nursing educational credit) in areas related to cerebrovascular disease.

In addition to professional education, the stroke center should have at least 2 annual programs to educate the public about prevention and recognition of stroke and the availability of acute therapies.

Documentation of educational programs can be achieved through continuing medical education credits for the professional staff. Evaluation questionnaires for the public educational programs should be reviewed and saved to document such programs.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Recommendations are based on a review of research-based evidence from randomized clinical trials and observational studies. A consensus of the Brain

Attack Coalition membership and others with expertise in stroke was used to supplement or develop areas not fully addressed in the literature.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall

The establishment of primary stroke centers may improve the level of care and standardize some aspects of acute care for patients with stroke. Expected benefits of primary stroke centers are:

- improved efficiency of patient care
- fewer peristroke complications
- increased use of acute stroke therapies
- reduced morbidity and mortality
- improved long-term outcomes
- reduced costs to health care system
- increased patient satisfaction

Stroke Units. Evidence from individual studies and from meta-analyses support the efficacy of stroke units in the care of patients with acute stroke. Compared with patients with stroke who receive care in general medical wards, patients who receive care in stroke units had a 17% reduction in death, a 7% increase in being able to live at home, and an 8% reduction in length of stay.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These proposed recommendations are not formal guidelines and are not intended to be used as credentialing criteria. Since there has not been a formal definition of a stroke center, data about the efficacy of stroke centers have not yet been generated. However, there are data about the efficacy of some of the key components of a stroke center, such as stroke units, care by a neurologist, and the use of tissue-type plasminogen activator (tPA). As the stroke center concept evolves, outcomes-based research must be performed to determine the efficacy of this approach. The members of the Brain Attack Coalition hope that these recommendations will begin a process by which the stroke center concept will evolve and grow. If the stroke center concept is accepted by the medical community, there may be a future need for the more formal process of credentialing or validating such centers.
- An important element of stroke care that has not been addressed in this article is rehabilitation. Although the guideline developer's focus has been on acute care, initiation of early rehabilitation can hasten recovery following

stroke. However, most of this rehabilitation occurs after the acute hospitalization and often in facilities remote from the acute care hospital. Stroke prevention is another area of importance. Many preventive therapies, such as antiplatelet agents or warfarin sodium, are highly effective, may be started during the acute hospitalization, and typically continue for many months or years.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Alberts MJ, Hademenos G, Latchaw RE, Jagoda A, Marler JR, Mayberg MR, Starke RD, Todd HW, Viste KM, Girgus M, Shephard T, Emr M, Shwayder P, Walker MD. Recommendations for the establishment of primary stroke centers. JAMA 2000 Jun 21;283(23):3102-9. [69 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Jun

GUIDELINE DEVELOPER(S)

Brain Attack Coalition - Disease Specific Society

GUIDELINE DEVELOPER COMMENT

The Brain Attack Coalition includes representatives from the following organizations:

1. American Academy of Neurology
2. American Association of Neurological Surgeons
3. American Association of Neurosciences Nurses
4. American College of Emergency Physicians
5. American Heart Association
6. American Society of Neuroradiology
7. National Institute of Neurologic Disorders and Stroke (NIH)
8. National Stroke Association
9. Stroke Belt Consortium

SOURCE(S) OF FUNDING

Not stated

GUIDELINE COMMITTEE

Brain Attack Coalition

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Mark J. Alberts, MD; George Hademenos, PhD; Richard E. Latchaw, MD; Andrew Jagoda, MD; John R. Marler, MD; Marc R. Mayberg, MD; Rodman D. Starke, MD; Harold W. Todd; Kenneth M. Viste, MD; Meighan Girgus; Tim Shephard, RN; Marian Emr; Patti Shwayder, MPA; Michael D. Walker, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Dr. Alberts has received grant support from, is a member of the speakers bureau of, and has a consulting relationship agreement with Genetech, Inc., a manufacturer of tPA.

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available to registered subscribers from the Journal of the American Medical Association Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 5, 2001. It was verified by the guideline developer as of May 15, 2001.

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